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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,451

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Shlomit Wizel

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04/20/2006

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/791,451

Applicant(s)

WIZEL ET AL.

Examiner

Mark L. Berch

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/24/05. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-28, and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9803553 A1.

In WO 9803553 A1, see Example 11.

Claims 1-5, 7-30, 52-54, and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by 6,107,302 or WO 9725989 A1.

In 6,107,302, see examples 1B, 2B. In WO 9725989 A1, see example 2B.

Claims 1-5, 7-28, 42, and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by 4,957,924.

In 4,957,924, see Example 1B(b).

With regard to the compound claims, the references show the Valacyclovir hydrochloride, but are silent on the particular crystallographic form. MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

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Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also *Ex parte Anderson*, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, or ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture

products or to obtain and compare prior art products (footnote omitted).

Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the claimed form does not appear at all in the product, or if on repetition, it sometimes does not appear in the product, then the rejection is overcome.

With regard to the process claims 52-54, 42, and 57-59, it appears that largely the same process is being done, because the process claims are written rather broadly. Thus, for example, the method of claim 52 is met by the last sentence in WO 9725989. The process of claim 29 is met by 6,107,302, column 6, line 31, where the slurrying solvent in acetone. For claim 42, see 4,957,924, column 9, lines 5-7. For the composition claims, once the compound is dissolved in e.g. water, the crystalline form vanishes; all crystalline forms will give the same solutions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over 6,107,302 or WO 9725989 A1.

Claim 55 calls for methanol. The references use ethanol. However, lower alcohols are taught generically. See e.g. 6,107,302 column 3, line 41, so such a variation would be obvious as taught by the reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 32-33, 37, 38-41, 44-47, 49-50, 57-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1. Claims 49 and 57 are missing the “hydrochloride” in the first line.**
- 2. Claim 62 lacks a carrier. A complete and proper composition claim must recite a carrier, otherwise it is just a compound claim.**
- 3. Claim 63 is improperly dependent on claim 53, which is a process claim.**
- 4. The last word in claim 29 is misspelled, and also in claim 37, third from last solvent..**
- 5. The first listed solvent in claim 33, step a is misspelled.**
- 6. Claims 44-47, 49-50, 57-61 are incomplete. The preamble requires a crystalline form.**

But the claims, except for claim 60, stop at the suspension. The material in a suspension has not crystalline form. Some essential process is needed. Claim 60 says “isolating” but such term is completely generic, saying what the result is, but not how the crystalline form is actually obtained.

- 7. Claim 32 presumably should depend on claim 31.**

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Claims 42 and 57 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

There is an ambiguity with regard to claims 42 and 57. The same physical step is involved in both claims. Note that IPA is a lower alcohol. According to claim 57, one gets the monohydrate. According to claim 42, one gets the form V. It appears possible that the claims are not written properly; perhaps the wrong solvent was named. (Paragraph 2). Alternatively, an essential feature may be missing from the claim, which directs the process either to the hydrate or to form V. MPEP 2164.08(c) states, "A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). This is proper "when the language of the specification makes it clear that the limitation is critical for the invention to function as intended." Assuming that this is true, applicants need to insert into either claim 42 or 57 the missing feature that will direct the process in the direction of obtaining the product required by the preamble.

Claim Objections

Claims 2-5 are objected to as duplicating claim 1; claims 8-11 duplicate claim 7; claims 13-16 duplicate claim 12; claim 16 duplicates claim 15; claims 18-22 duplicate claim 17; claims 24-25 duplicate claim 23; claims 27-28 duplicate claim 26. Thus, claim 2-5 just describe the material in greater detail, or set forth aspects of the same thing. This is the

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exact same thing as claim 1. Claim 2 simply describes it in a bit more detail, but the product is identical. It is not possible to infringe claim 1 without infringing claim 2 and vice versa.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28, 31-32, 62-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 25-28, 30-34, 36-39, 41-44 of copending Application No. 11042538. Although the conflicting claims are not identical, they are not patentably distinct from each other because There is no line of demarcation. Claims 36-39 of 11042538 will cover any form, and the claims of 10791451 would cover such purity levels. Claims 31-32 of 10791451 cover the isopropanol slurry process of claims 22, 25-28, 30-34 of 10791451

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 31-41, 44-51, 57-61, 64 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26 of prior U.S. Patent No. 6849736. This is a double patenting rejection. Applicants have already patented these claims in the parent.


Claims 1-64 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-64 of copending Application No. 11042526. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicants have filed identical claims in both cases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.


**Mark L. Berch
Primary Examiner
Art Unit 1624**

April 17, 2006